DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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Smith & Nephew, Incorporated
Allison Chan
Regulatory Affairs Specialist
7135 Goodlett Farms Parkways
Cordova, Tennessee 38018

October 28, 2015

Re: K150241
Trade/Device Name: Genesis II XLPE Resurfacing Patellar Components
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH, MBH, KRO, KRR
Dated: September 25, 2015
Received: September 28, 2015

Dear Ms.Chan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150241

Device Name
Genesis II XLPE Resurfacing Patellar Components

Indications for Use *(Describe)*
The Genesis II XLPE Resurfacing Patellar Components are intended to be used with Smith & Nephew Total Knee Systems and Patello-Femoral Replacement Knee Systems and their cleared Indications for Use.

Indications for Total Knee Replacement
1. Rheumatoid arthritis.
2. Post-traumatic arthritis, osteoarthritis, or degenerative arthritis.
3. Failed osteotomies, unicompartmental replacement, or total knee replacement.
4. Posterior stabilized knee systems are designed for use in patients in primary and revision surgery, where the anterior and posterior cruciate ligaments are incompetent and the collateral ligaments remain intact.
5. Constrained knee systems are designed for use in patients in primary and revision surgery, where the posterior cruciate ligament and one or both of the collateral ligaments (i.e. medial collateral and/or lateral collateral ligament) are incompetent.
6. Hinge knee systems are designed for use in patients in primary and revision surgery, where the posterior cruciate ligament and one or both of the collateral ligaments (i.e. medial collateral and/or lateral collateral ligament) are absent or incompetent.

Indications for Patello-Femoral Replacement
1. Degenerative arthritis in the distal femur and patella;
2. A history of patellar dislocation or patellar fracture; and
3. Failed previous surgery (arthroplasty, tibial tubercle elevation, lateral release) where pain, deformity or dysfunction persists.

The Smith & Nephew Patello-Femoral Implants are intended for implantation with bone cement.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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We are smith&nephew

510(k) Summary
Genesis II XLPE Resurfacing Patellar Components

Submitted by:	Smith & Nephew, Inc. 1450 East Brooks Road Memphis, Tennessee 38116
Date of Summary:	March 25, 2015
Contact Person and Address:	Allison Chan Regulatory Affairs Specialist T 901-399-1098 F 901-566-7022
Name of Device:	Genesis II XLPE Resurfacing Patellar Components
Common Name:	Knee prosthesis
Device Classification Name and Reference:	21 CFR 888.3560 Knee joint patellofemorotibial metal/polymer/metal semi-constrained cemented prosthesis 21 CFR 888.3565 Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis 21 CFR 888.3510 Knee joint femorotibial metal/polymer constrained cemented prosthesis 21 CFR 888.3540 Knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis
Device Class:	Class II
Panel Code:	Orthopaedics/87
Product Code:	JWH, MBH, KRO, KRR

Device Description

Subject of this Premarket Notification are the Genesis II XLPE resurfacing patellar components manufactured from highly cross linked polyethylene (XLPE) material. The Genesis II XLPE resurfacing patellar components are intended to be used with the following knee systems

- Smith & Nephew Total Knee Systems
- Smith & Nephew Patello-Femoral Knee Systems
- Competitor PFJ Patella-Femoral Knee Implants K051086
- Legion Hinge Knee System K081111
- Genesis II Constrained System K962137

Components of this premarket notification include

- Round and Oval Patellar components manufactured from highly cross-linked polyethylene (7.5 Mrad XLPE) material.

Intended Use

The Genesis II XLPE Resurfacing Patellar Components are intended to be used with Smith & Nephew Total Knee Systems and Patello-Femoral Replacement Knee Systems and their cleared Indications for Use.

Indications for Total Knee Replacement

1. Rheumatoid arthritis.
2. Post-traumatic arthritis, osteoarthritis, or degenerative arthritis.
3. Failed osteotomies, unicompartmental replacement, or total knee replacement.
4. Posterior stabilized knee systems are designed for use in patients in primary and revision surgery, where the anterior and posterior cruciate ligaments are incompetent and the collateral ligaments remain intact.
5. Constrained knee systems are designed for use in patients in primary and revision surgery, where the posterior cruciate ligament and one or both of the collateral ligaments (i.e. medial collateral and/or lateral collateral ligament) are incompetent.
6. Hinge knee systems are designed for use in patients in primary and revision surgery, where the posterior cruciate ligament and one or both of the collateral ligaments (i.e. medial collateral and/or lateral collateral ligament) are absent or incompetent.

Indications for Patello-Femoral Replacement

1. Degenerative arthritis in the distal femur and patella;
2. A history of patellar dislocation or patellar fracture; and
3. Failed previous surgery (arthroplasty, tibial tubercle elevation, lateral release) where pain, deformity or dysfunction persists.

The Smith & Nephew Patello-Femoral Implants are intended for implantation with bone cement.

Comparison of Technological Characteristics with the Predicate Device

The Genesis II XLPE resurfacing patellar components are substantially equivalent in design and fundamental scientific technology to the defined predicate devices and do not raise any new issues of safety and efficacy. At a high level, the subject and predicate devices are based on the following same technological elements

- Use only with cement and single use
- Same articular and cement interface geometry

No technological differences exist between the subject and predicate device.

Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Mechanical Testing

To further support a determination of substantial equivalence, non-clinical bench (mechanical) testing was conducted to support the material change from conventional polyethylene to highly cross linked polyethylene (XLPE) on the Genesis II resurfacing patellar components. Test results demonstrated that the proposed devices are substantially equivalent to the previously cleared predicate device. The specific types of non-clinical testing conducted are listed below.

- *Static Shear Testing*
- *Fatigue Shear Testing*

Substantial Equivalence Information

The substantial equivalence of the Genesis II XLPE resurfacing patellar components is based on it similarities in the indications for use, design feature, and operational principles to the predicate systems listed in the table below. In addition the change in material to highly crosslinked polyethylene is identical to the material in reference predicate K071071.

Table 5.1: Substantially Equivalent Primary Predicates to the Genesis II XLPE Resurfacing Patellar Components

Design Aspect Reviewed	Genesis II XLPE resurfacing patellar components	Genesis II Knee System	Anthem Total Knee System
510(k) Number	Subject 510(k)	K951987	K142807
Predicate Type	Not Applicable	Primary	Primary
Manufacturer	Smith & Nephew	Smith & Nephew	Smith & Nephew
Similar Indications for Use	Yes	Yes	Yes
Similar Sterilization Methods	Yes	Yes	Yes
Articulating Surface	Round and oval	Round	Round and oval
Material	XLPE	Patellar components - UHMWPE	Patellar components - UHMWPE

Conclusion

As previously noted, this Traditional 510(k) Premarket Notification is submitted to request clearance for the modified Genesis II XLPE resurfacing patellar components. Based on the similarities to the predicate components and a review of the mechanical testing performed, the devices are substantially equivalent to the above predicate knee systems.